

REMARKS

Claims 27-39 are pending in the present application and at issue.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

IV. The Rejection of Claims 27-35 and 38-39 under 35 U.S.C. 103

The Office maintained the rejection of claims 27-35 and 38-39 under 35 U.S.C. 103 as being unpatentable in view of Bedford et al. (WO 96/05739) in view of Snow-Brand-Milk-Prod. (JP 02255081). This rejection is respectfully traversed.

As explained in prior responses, Snow-Brand-Milk-Prod. discloses a *Nocardiopsis* protease. However, Snow-Brand-Milk-Prod. does not teach or suggest the use of proteases in animal feed.

Bedford et al. disclose an enzyme feed additive comprising a xylanase, a protease and optionally a beta-glucanase, wherein the ratio between the xylanase and beta-glucanase activities lies within a certain specified range. At page 25, lines 2-5, Bedford et al. disclose that the protease is a subtilisin which can be derived from the genus *Bacillus*. Bedford et al. further disclose that the protease may be one of the following commercially available proteases: NEUTRASE™, PURAFECT™, SAVINASE™, MAXACAL™, DURAZYM™ and MAXAPEM™, or a mutant subtilisin described in one of a number of published patent applications. None of the proteases disclosed in Bedford et al. are acid-stable.

The feed additives described in Bedford et al. are said to have an improved (i.e., lower) feed conversion ratio (FCR), which results in more efficient utilization of the feed. However, the results shown in Bedford et al. do not prove Bedford et al.'s allegations of improved FCR.

The only experiments using a protease described in Bedford et al. are provided in Examples 2 and 5. However, as explained in the prior response, the results disclosed in the examples do not suggest to one of ordinary skill in the art that there is an improvement in FCR by using a protease in an animal feed.

In the experiment described in Example 2, chickens were treated with a control animal feed (with no enzymes), an animal feed designated "Z", which is identical to the control except that it also contains xylanase, three animal feeds designated "A," "C," and "E", which are identical to Z except that they contain the protease NEUTRASE™, and three animal feeds designated "B," "D" and "F", which are also identical to Z except that they contain a modified *Bacillus amyloliquefaciens* subtilisin.

The results, which are provided in Table 4, show that the use of the control animal feed and the animal feed designated Z resulted in an FCR of 1.85, the use of the animal feeds designated A, C and E resulted in an FCR of 1.85, 1.85 and 1.82 (i.e., two of the animal feeds containing the protease NEUTRASE™ resulted in the same FCR as the control animal feed and the animal feed designated Z), and the use of the animal feeds designated B, D and F resulted in an FCR of 1.82, which is only a fraction below the FCR obtained with the control animal feed and the animal feed designated Z. The results do not demonstrate that there is any statistical significant difference between the results obtained using the control animal feed and the animal feed designated Z, on the one hand, and the results obtained using the animal feeds designated A-F, on the other hand. Thus, the results of Example 2 would not suggest to one of ordinary skill in the art that there is an improvement in FCR by using a protease in an animal feed.

Similarly, the results in Example 5 shown in Table 9, do not demonstrate that there is any statistical difference between using a protease-free animal feed and a protease-containing animal feed. Thus, the results of Example 5 also would not suggest to one of ordinary skill in the art that there is an improvement in FCR by using a protease in an animal feed.

That the results in Bedford et al. do not show an improvement in FCR by using a protease is confirmed in the Declaration under 37 C.F.R. 1.132 of Carsten Sjøholm, which was filed during prosecution of the parent application and submitted with the prior response. Mr. Sjøholm explains that the results disclosed in Bedford et al. do not prove to one of ordinary skill in the art that the addition of a protease to an animal feed results in an improved feed conversion ratio.

Applicants also previously submitted a copy of a Declaration under 37 C.F.R. 1.132 of Anna-Maria Klünter, which was also filed during prosecution of the parent application. The Klünter declaration describes a set of experiments in which chickens were fed feed compositions with or without the *Nocardiopsis* protease of SEQ ID NO: 1. Dr. Klünter reports that the results of the experiments “clearly demonstrate that broiler chickens have a significantly improved weight gain and significantly improved feed conversion when fed an animal feed composition comprising the *Nocardiopsis* protease.” Dr. Klünter also concludes that the results are surprising and unexpected.

These results demonstrate that broiler chickens have a significantly improved weight gain and significantly improved feed conversion when fed an animal feed composition comprising an acid-stable protease. The acid-stable proteases recited in the claims differ significantly in structure (low identity) and function (acid stability) from the proteases of Bedford et al. Based on the general knowledge in the art and in particular, Bedford et al., an artisan would not expect that all proteases are suitable for use in feed let alone that the acid-stable proteases recited in the claims of the present invention would be useful for improving the nutritional value of feed.

Notwithstanding Applicants' showing of surprising and unexpected results, the Office stated that "The affidavits of 2/15/08 do not support the entire scope of elected claims." This is respectfully traversed.

As explained in the prior response, the proteases recited in Applicants' claims are structurally similar to the protease of SEQ ID NO: 1 (90-95% identical) and therefore would be expected to have properties similar to the protease of SEQ ID NO: 1.

Moreover, Applicants enclose a Second Declaration under 37 C.F.R. 1.32 of Anna-Maria Klünter. The Klünter second declaration describes a set of experiments in which chickens were fed feed compositions with or without a protease from *Nocardiopsis* DSM 43235 having an amino acid sequence of amino acids 1-188 of SEQ ID NO: 2 disclosed in WO 2004/111220, which is about 83.5% identical to the sequence of SEQ ID NO: 1 (*Nocardiopsis* sp. NRRL 18262 protease) disclosed in the above-identified application. Dr. Klünter reports that "the results demonstrate that broiler chickens have a statistically significant improved feed conversion when fed an animal feed composition comprising the *Nocardiopsis* DSM 43235 protease."

Dr. Klünter also states that "These results demonstrate that proteases having an amino acid sequence which is highly homologous, e.g., at least 90% identity, to the sequence of SEQ ID NO: 1 of the instant application would also result in an improved nutritional value of the feed."

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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